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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

THE NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION PLAINTIFFS' REPLY IN SUPPORT OF SUMMARY JUDGMENT FOR PLAINTIFFS

February 27, 2020
With Oral Argument: 10:00 a.m.

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INTRODUCTION

Defendants' opposition to Plaintiffs' motions for summary judgment ("HHS Opp."), ECF No. 131, ignores central legal obligations for agency notice-and-comment rulemaking, fails to cite even a single comment or any other factual evidence from the administrative record, and asks this Court to rubberstamp an agency decision-making process riddled with arbitrariness. The Department of Health and Human Services and its officials (collectively "HHS") urge this Court to uphold their sweeping Title X rulemaking based only on their conclusory statements and references back to a different rulemaking three decades ago, even though the evidence that was before HHS in the 2019 administrative record overwhelmingly *contradicted* HHS's conclusory assertions. In fact, the 2019 record made clear that proceeding with this Rule would severely harm the core health care purpose of Title X, costing its patients and providers dearly. *See* ECF No. 121 ("NFPRHA Mot.") at 1-72 & ECF No. 122 (record excerpts); ECF No. 118 ("WA Mot.") at 15-34 & ECF No. 119 (record excerpts).

Rather than trying to contend with Plaintiffs' well-documented showing that this rulemaking exemplifies arbitrary and capricious agency action, *id*., Defendants' latest brief repeats faulty assertions from their opening brief. In addition, Defendants now falsely contend that Plaintiffs' argument is that "the Court can substitute its judgment" for that of the agency. HHS Opp. at 2. On the contrary, Plaintiffs properly ask this Court to test HHS's rulemaking process against the Administrative Procedure Act ("APA")'s standards for decision-making, and to vacate the Rule because the agency has not engaged in the reasoned

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rulemaking the law requires for valid administrative action. Indeed, the Supreme Court has often emphasized the importance of courts carefully examining whether an agency has engaged in a process of cogent explanation rooted in the record facts, because without such a reasoned process, bare invocation of agency "expertise"—as Defendants attempt to rely on here—can "become a monster which rules with no practical limits." *Motor Vehicle Mftrs. Ass'n v. State Farm Mut. Auto Ins. Co*, 463 U.S. 29, 48 (1983) (internal quotation omitted).

Because Defendants simply sidestep Plaintiffs' record-based showing that this rulemaking was shot through with unreasoned and damaging agency choices, and argue against straw men, Defendants' opposition fails to undercut Plaintiffs' showing of arbitrary rulemaking in any way. This reply brief, therefore, does not revisit that detailed showing, *see* NFPRHA Mot. 1-72 & i-iii (Table of Contents list of HHS's pervasive rulemaking failures); ECF. No. 122 (record excerpts); WA Mot. at 15-34; ECF No. 119 (record excerpts). Instead, this reply brief first highlights and corrects HHS's efforts to evade essential legal standards for valid decision-making under the APA. *Infra* Part I. It then addresses just some of the mischaracterizations of Plaintiffs' arguments and other ways in which Defendants' opposition erroneously attempts to deflect attention from the reality of their unreasoned decision-making. *Infra* Part II. Finally, this reply shows that HHS's pleas for delay and for only a partial vacatur of the Rule are unfounded. *Infra* Part III. No additional steps need occur before the APA's protections against arbitrary rulemaking are enforced, the Rule is vacated in full, and the Title X program is

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saved from this harmful rulemaking—including its sweeping physical, staff, and systems separation mandate set to take effect on March 4, 2020.[1]

ARGUMENT

I. Defendants' Arguments Disregard Important Legal Standards That Agencies Must Satisfy to Ensure Non-Arbitrary Decision-Making

A. An Agency Cannot Ignore Its Own Contrary Factual Findings

Defendants attempt to evade a required component of reasoned decision-making when an agency reverses course: As the Ninth Circuit *en banc* has emphasized, "if the 'new policy rests upon factual findings that contradict those which underlay its prior policy,'" the agency "*must include* 'a reasoned explanation … for disregarding facts and circumstances that underlay or were engendered by the prior policy.'" *Organized Vill. of Kake v. U.S. Dep't of Agriculture*, 795 F.3d 956, 966 (2015) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)) (emphasis added); *accord Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). "Unexplained inconsistency … is a reason for holding an interpretation to be an arbitrary and capricious change." *Kake*, 795 F.3d at 966 (internal quotation omitted); *see also Encino*, 136 S. Ct. at

[1] To avoid duplication, the NFPRHA Plaintiffs reply here with regard to Plaintiffs' APA arbitrary and capricious claims and the proper remedy for all claims, while the State of Washington replies regarding the APA logical outgrowth claims and Plaintiffs' other statutory and constitutional claims. The NFPRHA Plaintiffs adopt in full and incorporate by reference the Washington reply brief filed today.

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2127; *Washington v. Azar [II]*, No. 2:19-cv-00183-SAB, 2019 WL 6219541 at *2 (E.D. Wash. Nov. 21, 2019).

HHS in 2019 decided to adopt a Rule that contradicted its own factual findings in its 2000 rulemaking and in HHS's 2014 clinical standards for family planning (the "QFP")—both of which specified that (a) pregnancy testing and counseling is a necessary family planning service; (b) pregnancy counseling must respond to patient values and needs, not provider preferences; (c) pregnancy counseling includes referral at patient request; and (d) referral of all pregnant patients for prenatal care is not appropriate. *See* NFPRHA Mot. at 11-30 (including citations therein). In its 2019 rulemaking, the agency failed to address these prior HHS factual findings and failed to even attempt to explain why, inconsistently, the Rule now deems pregnancy testing and counseling an optional service; lets providers determine the scope of that counseling, regardless of patient preferences; bars abortion referrals even when patients request them; and inaccurately deems referral to prenatal care "medically necessary" for all. *Id.*

Likewise, after HHS in 2000 found a similar (though less onerous) physical separation scheme from 1988 of "little relevance" to Title X and "unenforceable"—with ambiguities and line-drawing difficulties that the agency in 2000 found unlikely ever to be resolved—the agency in 2019 ignored those factual findings. After HHS had encouraged grantees and their providers to build enduring programs under the 2000 regulations and related compliance guidance, the agency in 2019 ignored that reliance within the Title X network. HHS simply jettisoned

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these historical facts underlying and engendered by its 2000 rulemaking. NFPRHA Mot. at 3-6, 36-54.

In doing so, HHS attempted to skip over its own explicit learning after 1988, and to turn the clock all the way back to 1988 without providing a "detailed justification" for abandoning the agency's *more recent* factual findings and decades-long program reliance. HHS attempted this same sleight-of-hand in the religious refusals rulemaking and litigation, but the courts there correctly rejected HHS's bid to reenact 2008 regulations without substantively addressing *later* HHS factual findings that had caused the agency to rescind the 2008 regulations in 2011. *See New York v. HHS*, No. 1:19-cv-04676, 2019 WL 5781789 at *45-50 (S.D.N.Y. Nov. 6, 2019); *Washington v. Azar II*, 2019 WL 6219541 at *11. It is not enough to acknowledge a policy change and offer purported explanations that *never contend with* the agency's previously operative factual findings and its program's longstanding reliance. *Cf.* HHS Opp. at 17 (arguing that the agency "need not" address the factual underpinnings of its prior policy).[2] As *Encino* teaches, conclusory statements about a now-favored statutory interpretation are not reason enough to abandon an agency's own, contrary factual findings. 136 S. Ct. at 2126-27. When the "agency ignores or countermands its earlier factual findings without

[2] HHS falsely asserts that its rulemaking considered "reliance interests," HHS Opp. at 24, when that topic is nowhere discussed in the rulemaking; HHS's briefs offer no support for this bald contention. *See also* NFPRHA Mot. at 37-41.

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reasoned explanation for doing so," it violates the APA. *Azar II*, 2019 WL 6219541 at *2.

B. Agency Rulemaking Must Be Rooted in Available Facts, Must Rationally Present Both Costs and Benefits, and Must Be Cogently Explained; It Cannot Simply Be Declared Regardless of Evidence

In addition to the above, Defendants ignore and fail to satisfy numerous other fundamental legal requirements for agency rulemaking. For example:

1. Though Defendants nod toward the Supreme Court's *State Farm* decision, HHS Opp. at 15, they nowhere mention or attempt to address its principle that agencies act arbitrarily if they offer an explanation "that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. As Plaintiffs have already shown, HHS's rulemaking explanations conflict over and over again with the record evidence. NFPRHA Mot. at 18-72.

2. Likewise, agency decision-making cannot rest on "sheer speculation." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708-09 (D.C. Cir. 2014). Just as the FCC had not explained its $75 number in *Sorenson* and thus violated the APA, it is undisputed here that HHS's Title X rulemaking had no substantiation for the implausibly low dollar cost that HHS plucked out of thin air and relied upon for physical separation, despite the ready availability of cost information in the record and elsewhere. NFPRHA Mot. at 43-47. HHS's further, implausible speculation that Title X providers might have spare facilities available, *see* HHS Opp. at 27-28, does nothing to ground HHS's cost assessment in evidence, as required. *See Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1067-68 (9th Cir. 2018).

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3. Nor can an agency employ unbalanced decision-making, accepting and exaggerating hypotheses it favors, while rejecting countervailing evidence; in other words, the agency cannot put a thumb on the scale in assessing advantages and disadvantages. *See, e.g.*, *Azar II*, 2019 WL at *12 (finding that HHS's internally inconsistent treatment of anecdotal evidence regarding impacts on religious believers versus impacts on other groups rendered its rulemaking arbitrary and capricious). Yet HHS throughout the Title X rulemaking put a thumb on the scale: It prioritized and was especially solicitous of protecting unidentified, *hypothetical future providers* with conscience objections, for example, but ascribed zero cost to the Rule's harms on existing *Title X patients*, through the Rule's forced rejection of patient needs and requests, contradiction of patient beliefs, ending or moving of patients' Title X access points, severing their trusted patient-clinician relationships, diminishing patients' contraceptive choices, etc. NFPRHA Mot. at 18-72.

Defendants' brief has no answer on any of the above three legal standards. HHS's failure to satisfy even one is alone sufficient to establish that its rulemaking was arbitrary and capricious. Here, the agency has ignored and violated all of them, as set forth more extensively in Plaintiffs' initial motion papers.[3]

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[3] Defendants also err as a matter of law in claiming that NFPRHA's members are "in no position to object" to what the Rule allows others to do. HHS Opp. at 32 n.10. In the context of a competitive grant program, current and future competitors—including hundreds of NFPRHA's members here—have standing to complain when the agency changes the program's terms, seeks to increase

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4. In addition, Defendants' brief fails to address *National Lifeline Assoc. v. FCC*, 921 F.3d 1102 (D.C. Cir. 2019), and its explanation of why, within a federal social service program dependent on non-federal providers for its success, providers' business models, willingness to participate under the proffered federal terms, and reliance are "important aspect[s] of the problem" necessary for an agency to rationally consider. 921 F.3d at 1111-15 (quoting *State Farm*, 463 U.S. at 43). Plaintiffs cited the *National Lifeline* case multiple times in their motion, yet Defendants persist in dismissing Title X providers' and other knowledgeable commenters' real-world concerns about providers' inability to continue in the program under the Rule as "threats" and as unprecedented considerations. HHS Opp. at 20. *National Lifeline* underscores they are not. Rather, the exhaustive documentation of (a) the pressures that would drive existing providers away from Title X—including conflicts with professional standards (as articulated, for example, by the QFP and by relevant medical associations), and the Rule's high financial and reputational costs—and (b) specific providers poised to leave the Title X network constituted important record evidence that the agency had an obligation to address in a reasoned rather than a dismissive way, *cf.* HHS Opp. at 20. It is not enough, as HHS did here, to rely on speculative new "incentives" when the record evidence contradicted the agency's professed hope for sufficient

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competition by others, and "tilts the playing field for parties that were already competing." *Planned Parenthood of Greater Wash. and Idaho v. HHS*, No. 18-35920, 2020 WL 111800 at *5 (9th Cir. Jan. 10, 2020).

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future providers and nationwide client service. *National Lifeline*, 921 F.3d at 111-15; *see also* NFPRHA Mot. at 15-50.

* * *

In sum, the legal standards that govern agency rulemaking did not give HHS carte blanche to declare what Defendants now call "predictive judgments," HHS Opp. at 2, 23, 28, no matter how far those departed from the agency's own prior findings of fact, the current administrative record, an evenhanded assessment of costs and benefits, and the realities of accomplishing Title X's overall health care purpose. *See also* NFPRHA Mot. at 1-72. Contrary to Defendants' misstatements about Plaintiffs' claims to enforce these legal standards, Plaintiffs do not attempt to take the place of the agency, or to convince the Court to do so, or to engage in abstract policy arguments. HHS Opp. at 2, 15, 18. Plaintiffs, as their claims make plain, instead seek to enforce the essential process requirements of valid administrative agency decision-making. These process requirements are critical APA safeguards, including for patients, clinicians, and the public health, that constrain HHS's rulemaking but were repeatedly violated here.

C. Agency Decision-Making Is Evaluated as of the Time and on the Record Upon Which It Was Made; Here, the Record Foretold Massive Provider Departures and Severe Disruption, Yet HHS Ignored That Evidence

Remarkably, Defendants' opposition brief persists in urging a reality today that the Court can plainly see is not true. Back in its rulemaking, HHS claimed that the Rule would "lead to an increase in the number of health care providers who apply and receive funding under the Title X program, thus decreasing" gaps in service. 84 FR 7780; HHS Opp. at 21. Defendants now argue counterfactually to

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this Court that "those predictions have been borne out" by "subsequent events," HHS Opp. at 21-22, even though the Rule—as shown by Defendants' own published provider directories—has in its first six months *diminished the number of Title X providers by the hundreds* and led to not a single new grantee, but rather to *statewide gaps* in five states and other new, major holes in the program's supposedly nationwide coverage. *See* NFPRHA Mot. at 24-35.

Even more importantly—because this rulemaking must be judged as of the time it occurred—the administrative record before HHS when it adopted the Rule repeatedly documented that such widespread provider departures *would* occur as soon as it took effect, yet HHS erroneously disregarded that evidence. *See* NFPRHA Mot. at 20-26, 41-48. HHS tried to find cover for ignoring that evidence by asserting that it could not precisely anticipate the exact number of provider losses. *See* HHS Opp. at 22 (quoting 84 FR 7782). But when a serious negative impact is clear from the administrative record, an agency cannot ignore that fact because its exact quantity may be imprecise. NFPRHA Mot. at 48; *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) (uncertain magnitude is "no justification for disregarding the effect"); *Stewart v. Azar*, 366 F. Supp. 3d 125, 138 (D.D.C. 2019) (rejecting HHS action that failed to provided reasoned response to "undoubtedly substantial" Medicaid coverage losses); *see also New York v. HHS*, 2019 WL 5781789 at *51 ("HHS's meager and non-committal responses are manifestly inadequate to the problems squarely before the agency"). In promulgating the Rule, HHS violated this well-established requirement for reasoned decision-making and completely dismissed the

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impending serious harms from provider departures and network disruption, contrary to the record evidence. NFPRHA Mot. at 20-26, 41-48.

Now, HHS compounds its errors by claiming that "subsequent events" are properly part of the Court's examination of a rulemaking process under the APA. HHS Opp. at 22 n.6. It is settled law, however, that "agency action must be examined by scrutinizing the administrative record at the time the agency made its decision," and Defendants here claim none of the limited exceptions to that record rule. *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1159 (9th Cir. 1980); *see also Lands Council v. Powell*, 395 F.3d 1019, 1029 (9th Cir. 2005) (general rule that "courts reviewing an agency decision are limited to the administrative record"); *State Farm*, 463 U.S. at 51-57 (agency decision-making "must explain the evidence which is available" then and support its decision-making on the facts found and the choices made when it acted). Therefore, none of HHS's "subsequent events" or counterfactual assertions about the current size, composition, or coverage of the Title X network can save HHS's unreasoned decision-making in March 2019.[4]

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[4] As "subsequent events," HHS focuses on law suits brought by Obria and Vita Nuova, supposedly evidencing more Title X providers as a result of the Rule. HHS Opp. at 21. Obria, however, became a grantee under the 2000 regulations before the Rule took effect, and its limited Title X participation in California is hugely overshadowed by the much more widespread provider departures there caused by the Rule. *See* NFPRHA Mot. at 34-35. And as HHS itself emphasized in Vita Nuova's law suit, that entity may have no employees, has never applied for

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II. Defendants' Efforts to Distract from the Rulemaking's Arbitrariness Fail

In addition to the legal errors discussed above, HHS's opposition brief consists of other, diversionary tangents that fail to meet Plaintiffs' arguments. Defendants mischaracterize Plaintiffs' arbitrary and capricious arguments, or pull one small part of an argument out of context, to attack various straw men. But Defendants never attempt to show, much less succeed in showing, factual grounding in the record and reasoned, non-conclusory explanations for the Title X rulemaking decisions challenged here. Plaintiffs briefly correct examples of Defendants' misdirection below, and refer the Court back to Plaintiffs' earlier briefing for their full showing of all of the failures in HHS's 2019 rulemaking process, *see* NFPRHA Mot. at 1-72; WA Mot. at 15-34.

First, HHS's opposition brief tries to deflect the agency's unexplained rejection of numerous prior HHS *factual findings*, and thus failure to comply with *Encino, Fox Television,* and *Kake*, by arguing as if Plaintiffs' claim were that HHS had failed to acknowledge its changes in regulatory text or in *legal* interpretations. *See* HHS Opp. at 16-18, 24. Plaintiffs have been explicit, however, that unaddressed contrary factual findings and reliance are one of the central ways in which HHS's decision-making was unreasoned. NFPRHA Mot. at 11-18, 36-42. Reverting to a discussion of HHS's legal assertions in no way addresses the

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HHS funds, and has not even pled facts "demonstrating that Vita Nuova would be a qualified applicant (or subrecipient) for Title X funds." *Vita Nuova, Inc. v. Azar*, No. 4:19-cv-00532 (N.D. Tex), HHS Motion to Dismiss, ECF No. 17 at 2, 14, 16.

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contrary factual findings and decades-long reliance associated with the agency's prior positions, and just further exposes the arbitrariness of HHS's 2019 actions.

Second, this case is not *Rust v. Sullivan*, 500 U.S. 173 (1991). Plaintiffs' arbitrary and capricious claims are not controlled by *Rust*, nor can HHS justify its 2019 rulemaking by pointing to *Rust*'s characterizations of the Title X program back in 1988 or 1991. Since *Rust*, Congress has made it clear that pregnancy counseling *is* a Title X service, and that the program is *not* an exclusively "preconception" one, *cf.* HHS Opp. at 19. In addition, not only has Congress annually since 1996 made clear that pregnancy counseling falls within the Title X program, but HHS itself published guidance, at the same time as its 2000 regulations, to provide additional clarity to grantees on how to handle abortion-related activities. 65 FR 41281-82. Whereas HHS and *Rust* had relied on government reports from the 1980s citing a need then for clearer "operational guidance," *Rust*, 500 U.S. at 187, HHS's 2019 rulemaking failed to substantiate any confusion or even "potential for confusion" today, HHS Opp. at 23. The agency cannot support today's rulemaking—with its different pregnancy counseling scheme, different physical separation factors, new infrastructure spending constraints and grant-making criteria, and many additional restrictions not attempted in 1988—by citing decision-making upheld in *Rust* three decades ago. *See Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008) ("What was a reasonable balancing … twenty years ago may not be a reasonable balancing" in agency rulemaking today.).

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Third, HHS's passing dismissal of "medical ethics" in the rulemaking in no way provided a reasoned response to the medical ethical objections and the massive evidence of imminent provider departures in the 2019 administrative record. *Cf.* HHS Opp. at 18-20. To begin with, HHS's rulemaking (like its litigation argument) does not attempt to counter the record evidence on the substance of providers' medical ethical obligations at all. Instead, HHS merely sidesteps to sources *outside* medical ethics, such as legal protections for conscience or "the outcome in *Rust.*" HHS Opp. at 18-20; *see also* 84 FR 7748. It is not a reasoned response to a serious rulemaking concern to change the subject or respond in *non sequiturs*.

In addition, the many comments submitted to HHS from the very authorities that wrote and interpret the ethical codes for physicians, physician assistants, nurses, and social workers in this country unanimously contradicted HHS's bare conclusion that medical ethical concerns under the Rule were "misplaced," HHS Opp. at 18; *see also* 84 FR 7748. HHS's bald "disagree[ment]" with such significant record evidence, without engaging with its substance or pointing to any contrary medical ethical interpretations, was arbitrary and capricious. 84 FR 7748; *see* NFPRHA Mot. at 20-24; *State Farm*, 463 U.S. at 43.

Furthermore, the 2019 record evidence from medical authorities, government officials, academics, providers, and others demonstrating that the Rule would drive many organizations and clinicians away from Title X care did not rest solely on medical ethical conflicts, *cf.* HHS Opp. at 18, 20, though those were certainly one part of the avalanche of evidence. Commenters also made clear that,

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e.g., the QFP's principles, other clinical practice standards from leading authorities that HHS itself had endorsed, and clinicians' bedrock aim not to rebuff patient questions and undermine trust all conflicted with the Rule and would drive large numbers of providers away and discourage new ones. *See* NFPRHA Mot. at 13-27, 36-48. Regardless of whether HHS acknowledged or agreed with the ethical conflicts, the record was abundantly clear that immediate, widespread provider departures—including all Planned Parenthood sites—would follow if the Rule's pregnancy counseling restrictions took effect. *Id.* at 25-26. Yet HHS irrationally attributed no network disruption or negative impact on patient care to the Rule.

Fourth, HHS does not get a pass from the APA's reasoned decision-making standards by claiming it "weigh[ed] costs and benefits" or acted "sensibly." HHS Opp. at 23. As Plaintiffs have already explained at length, any "weighing" is arbitrary when the agency has put a thumb on the scale and claimed benefits and costs starkly different than the record evidence supports, as here. HHS's process did not at all resemble the FCC's in *Consumer Electronics Ass'n v. FCC*, 347 F.3d 291 (D.C. Cir. 2003), though HHS tries to find shelter in that case, HHS Opp. at 18, 23. In *Consumer Electronics*, the FCC had specific data ("substantial evidence") documenting a problem, and rested its assessment of costs to respond to that problem on its own long-term data gathering and on specific comments with dollar values. The court found that the FCC's analysis had "adequately estimated the long-term costs." 347 F.3d at 300-303. In stark contrast here, HHS identified no evidence of a present problem that needed to be addressed; relied on randomly chosen dollar numbers (not record evidence) for the financial cost of compliance;

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did not even consider large categories of obvious costs, including for providers and patients; failed to consult its own historical records of Title X budgets and operating costs; ignored its own QFP and its own previous factual findings; and discounted direct evidence of impending provider departures—all while hypothesizing various benefits of the Rule that lacked any evidentiary support (e.g., "more clients being served, gaps in service being closed, and improved client care," HHS Opp. at 25). *See* NFPRHA Mot. at 2-54. This is precisely the kind of faulty "weighing" or "judgment" process that must be set aside under the APA, because it does not reflect reasoned agency decision-making rooted in record fact.

Likewise, simply urging in litigation that a Rule's arbitrary line-drawing and internal inconsistencies are "sensible," *see, e.g.*, HHS Opp. at 23, 35, cannot make up for the agency's complete failure to acknowledge and rationally explain consequential distinctions in the rulemaking. *See Crickton v. Thomas*, 579 F.3d 978, 987 (9th Cir. 2009) (courts may not accept counsel's "post hoc rationalizations" for agency action). This rulemaking process was arbitrary and unreasoned, for example, in deciding to restrict what the Rule calls "nondirective" pregnancy counseling to only the most highly trained clinicians, Section 59.14(b)(1)(i), while placing no limit on who might advise pregnant patients about "maintaining the health of the … unborn child," Section 59.14(b)(1)(iv). Both discussions involve counseling "concerning a medical condition (pregnancy)," HHS Opp. at 23, yet the Rule treats them differently without explanation. HHS's definition for those costly, highly trained clinicians ("APPs") is also arbitrary. That definition was not included in the proposed rulemaking, conflicted with

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HHS's own classification of Title X clinicians' practice areas in the Family Planning Annual Reports ("FPARs"), and required a graduate degree, above and beyond full licensing requirements for clinicians' scope of practice—with no justification in the rulemaking for restricting nondirective pregnancy counseling to such a very limited group. *See* NFPRHA Mot. at 27-29.

Fifth, Defendants cannot isolate small pieces of Plaintiffs' larger arguments or HHS's approach to try to shift the focus away from the fundamental irrationalities that thoroughly infected HHS's rulemaking. HHS, for example, discusses the possibility of grantee questions to program officers about physical separation. HHS Opp. at 25-26. But that in no way alters the full picture of a rulemaking replete with arbitrariness: HHS in 2019 resurrected a "physical separation" model that it had concluded in 2000 was "unworkable," of "little relevance" to Title X, not "likely ever to result in an enforceable compliance policy" consistent with the cost-effective delivery of family planning services, and "ambiguous," with inherent "practical difficulties of line-drawing in this area." NFPRHA Mot. at 36-37 (quoting 65 FR 41276-82). HHS did not in 2019 explain its rejection of those earlier factual findings. Instead, HHS in 2019 added physical separation factors that it had in 1988 decided to exclude as explicit factors, based on their excessive cost. NFPRHA Mot. at 41-42 (citing 53 FR 2938-41, 2945). HHS in 2019 also added unprecedented restrictions on Title X project infrastructure spending, even as it noted such support had historically been "essential" for Title X's effective functioning. NFPRHA Mot. at 37-42. In promulgating all these new requirements, HHS failed to provide any reasoned

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estimate of the many costs of compliance for providers and patients (e.g., ignoring 85% of Title X sites' separation costs, though the Rule requires all sites to separate from abortion-related activities); by contrast, the rulemaking offered irrational assertions of benefits, unsupported by record evidence. NFPRHA Mot. at 43-54.

HHS did offer grantees the possibility of raising questions with program officers about "ways" or "plan[s]" to comply with physical separation, HHS Opp. at 25, but did not (a) even try to factor in grantee and provider implementation costs associated with such back-and-forth efforts; (b) acknowledge the near impossibility of such an ad hoc, unpredictable process for Title X grantees typically dealing with many subrecipients and dozens, in some cases hundreds, of different sites, all differently situated, where Title X care occurs; or (c) try to explain how any such inquiries could undo the Rule's "unworkable" scheme—they could not. NFPRHA Mot. at 36-54. As Plaintiffs have demonstrated, HHS acted contrary to its own previous factual findings and to the administrative record; offered inadequate, conclusory explanations or none at all; used a "thumb on the scale" approach to costs and benefits; and failed to consider important aspects of the problems raised by physical separation and infrastructure limits. *Id.* The possibility, post-rulemaking, of grantees asking questions does not remedy any, much less all, of those failures.

Similarly, Defendants' opposition brief questions Plaintiffs' use of Section 59.18(c), HHS Opp. at 35 n.11, to illustrate the Rule's new "layers upon layers of compliance provisions, where no lack of compliance had been shown" (among Plaintiffs' many, many other examples). NFPRHA Mot. at 68-72. HHS adopted

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those new layers without rationally considering the record evidence of the significant burdens they imposed on Title X providers or their counterproductive siphoning off of funds and attention from Title X's family planning health care. *See id.* Section 59.18(c)—contrary to Defendants' innocuous description, HHS Opp. at 35 n.11—commands HHS to *keep adding* compliance requirements even beyond this rulemaking, stating that the "Department shall put additional protections in place to prevent possible misuse of federal funds," without cabining at all how HHS might impose those additional requirements (to address an unsubstantiated, non-existent problem). HHS offered no support or explanation for that 59.18(c) provision during its rulemaking process.

More broadly, the Rule's "compliance" mindset attempts to *inter alia*: require duplicate physical facilities, electronic systems, and staff in the name of "physical separation;" limit Title X projects' infrastructure support; restrict spending and require its categorization as "direct implementation … expressly permitted by this regulation" or "direct services," which are undefined terms and apparently not coextensive; require the most costly clinicians (APPs) for nondirective pregnancy counseling; add voluminous new grantee submissions and justifications (requiring input not just from all subrecipients but also from all referral "agencies or individuals" *outside* the Title X project) in every quarterly report and application; impose a sweeping new application eligibility hurdle; add federal layers of oversight related to state and local laws; and force more administrative steps before Title X projects can serve minors. NFPRHA Mot. at 2-72. As Plaintiffs have explained, HHS prioritized Section 1008 and adding more

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and more compliance steps, while losing sight of the fact that the *whole of Title X* defines the agency's mandate. *Id.*; *see also* HHS Opp. at 14 (attempting to refute the Rule's conflict with Title X overall, but focusing solely on its "consisten[cy] with § 1008"). HHS could not rationally add more and more "compliance" initiatives based on no showing of need when the record made plain that serious gaps in and harm to Title X family planning would result. NFPRHA Mot. at 2-72; *Nat'l Fed'n of Fed. Employees v. McDonald*, 128 F. Supp. 3d 159, 172 (D.D.C. 2015) (agency cannot focus on implementing one statutory phrase to "undermin[e] the purpose of the statute itself").

Sixth, properly seeking judicial review is not "Monday-morning quarterback[ing]." HHS Opp. at 33. It is the important role of litigation like this to hold HHS to the APA's well-established standards for agency rulemaking. Those standards require a process that, *inter alia*, examines and rationally responds to well-founded, significant objections in the administrative record, rather than dismissing them with conclusory or unresponsive assertions, and provides a reasoned justification for agency line-drawing and inconsistencies, including those internal to a rulemaking. *See, e.g.*, *State Farm*, 463 U.S. at 41-57 (an agency must "examine the relevant data" and "cogently explain" its choices in light of the record facts); *District Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) ("We have often declined to affirm an agency decision if there are unexplained inconsistencies in the final rule."). Otherwise, agency notice-and-comment rulemaking is a capricious charade and a bare exertion of political power. *See Kake*, 795 F.3d at 971 (Christen, J. and Thomas, C.J., concurring) (regardless of

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change in administrations, "the law requires that the agency provide a reasoned explanation," and courts must entertain and impartially adjudicate such rulemaking challenges). But here, the agency repeatedly failed to respond to serious record objections and left numerous internal inconsistencies in the Rule unaddressed.

For example, HHS removed the agency's long-standing focus on "medically approved" contraceptive methods, contrary to the QFP's principles and to HHS's own, effective enforcement of that "medically approved" phrase in the Title X program for two decades. NFPRHA Mot. at 57-59. The Rule endorses Title X providers offering only one method of family planning to patients (so long as just one site in a project that spans an entire state or other large geographic area offers some other methods), contrary again to HHS's own 2014 QFP recommendations. *Id*. And the Rule newly invites into the Title X program providers that have a religious *objection* to almost all contraceptive methods. *Id*. When confronted with a chorus of warnings from ACOG, the AMA, the APHA and other leading health care experts that HHS was harmfully lowering the bar and undermining the care available to millions of vulnerable patients, *id.*, HHS responded only with conclusory assertions that never confronted these provisions' collective negative impact on access to effective contraceptives—the original motivating purpose behind Title X.[5] NFPRHA Mot. at 2, 57-59; *see generally Washington v. Azar II*,

[5] Contrary to Defendants' argument, Plaintiffs complaint about HHS's rulemaking decisions (including its removal of "medically approved") is not with Congress, HHS Opp. at 31; it is with HHS's arbitrary and harmful misuse of the agency's

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2019 WL 6219541 at *12 (it "seems elementary that increasing the number of medical professionals who would deny care based on religious or moral objections would not increase access to care; instead, access to care will deteriorate").

Similarly, the record comments and HHS's own drafting in the rulemaking made apparent that there were internal inconsistencies with no reasoned basis in:

- Section 59.5(a)(12) giving the conflicting and confusing commands of "must" and "should" in the text of that one provision;
- Section 59.5(a)(12) blocking Title X sites not in "close proximity to" primary health care providers, even as HHS said it aimed to expand Title X care via the Rule;
- HHS's inconsistent rulemaking statements that Title X would not subsidize collocated (non-Title X) primary care, but somehow *would* subsidize collocated (non-Title X) abortion-related care;[6]

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powers. Agencies possess rulemaking powers to fill in details and implement congressional programs in order to further those programs' aims. But HHS here irrationally contradicted its own expert findings about proper clinical practices and enabling patients' ready access to modern, effective contraceptives to *undermine* rather than further the program that Congress created.

[6] Defendants add more confusion and inconsistency by now arguing as if collocated (non-Title X) pregnancy counseling by primary care providers, including abortion referral upon request, could occur "onsite *at a Title X project*" yet still somehow be "kept separate" and compliant with physical separation. HHS Opp. at 30 n.8 (emphasis added).

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- Section 59.7(b) imposing an elaborate, non-objective eligibility requirement for applicants, contrary to the Title X statute's eligibility provisions and to HHS's general grant-making regulations and procedures; Defendants wrongly claim that "[n]one" of this "complexity is new in this Rule," HHS Opp. at 33;

- Section 59.7(c) requiring some applicants to compete on their "ability to procure a broad range of diverse subrecipients," including nontraditional providers, while other applicants need not do so;

- Section 59.2(1) imposing a more exacting obligation on Title X projects to press adolescents who seek to qualify for free care based on their own, limited financial resources to involve their families, while a less exacting standard, *see* Section 59.5(a)(14), applies to those adolescents who can otherwise pay for care; and

- Section 59.2(2) giving women who happen to work for employers with "conscience" objections to contraceptives a unique offset to their income *not* given to other Title X patients, for purposes of calculating eligibility for free or reduced-fee Title X services.

NFPRHA Mot. at 54-72. HHS arbitrarily proceeded to finalize the Rule without resolving or justifying *any* of these internal inconsistencies. *Id*.; *see also Lilliputian Systems, Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014) ("As a general matter, an agency cannot treat similarly situated entities differently unless it 'support[s] th[e] disparate treatment with a reasoned explanation and substantial evidence in the record.'") (alteration in original) (citation omitted). These irrationalities that HHS decided to leave unresolved in the Rule, despite commenters' confusion and objections, *see* NFPRHA Mot. at 54-72, highlight the agency's single-minded determination to push through a rulemaking that on so many levels would constrain and confuse, rather than advance, Title X care.

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Finally, the harmful, arbitrary aspects of this Rule are not "minor quibbles" to the Title X providers and patients subjected to them. HHS Opp. at 29 n.7, 34. The Rule, for example, forces clinicians to document specific efforts to convince adolescents to involve their family members in Title X care, including when the family has threatened the patient with violence or eviction, unless abuse has already occurred and an abuse complaint has already been filed with state authorities. NFPRHA Mot. at 66-67. This draconian provision exceeds statutory requirements, interferes with clinicians' exercise of their training and experience, and destroys provider-patient trust in a program where Congress specifically identified adolescents as one of the targeted recipients of its vital, confidential services. *Id.* Likewise, administrative and regulatory burdens that commenters explained would diminish Title X care, diminish all kinds of referral resources for Title X patients, and divert Title X funds away from the program's public purpose are not "quibbles" but central regulatory concerns that HHS failed to address in a reasoned way. *Id.* at 68-72. None are isolated regulatory failures. Instead, Plaintiffs have shown an arbitrary rulemaking process at every turn, where "prejudice is obvious" from HHS's unreasoned decisions large and small. *See Washington v. Azar II*, 2019 WL 6219541 at *2.

III. The Court Should Vacate the Rule in Full Without Any Delay

A. Vacatur of the Rule Is the Remedy the APA Requires in This Case

Defendants erroneously call vacatur an "extreme remedy" and in a footnote dispute its application to this case, but offer no legal argument or other support for that contention. HHS Opp. at 45 n.12. Vacatur is in fact "the presumptive remedy

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when a court finds an agency's decision unlawful under the Administrative Procedure Act." *AquAlliance v. U.S. Bureau of Reclamation*, 312 F. Supp. 3d 878, 880 (E.D. Cal. 2018); *accord Klamath-Siskiyou Wildlands Ctr. v. Nat'l Oceanic & Atmospheric Admin. Nat'l Marine Fisheries Serv.*, 109 F. Supp. 3d 1238, 1239 (N.D. Cal. 2015) ("[v]acatur is the standard remedy for unlawful agency decisions" in the Ninth Circuit); *see also Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [the agency's action] is not sustainable on the administrative record made, then the [agency's] decision must be vacated."); *W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir. 1987) ("An agency rule which violates the APA is void.").

This "follows from the text of the APA itself." *New York v. HHS*, 2019 WL 5781789 at *68. If this Court finds HHS's rulemaking "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," the Court "shall hold unlawful *and set aside*" the Rule. 5 U.S.C. § 706(2)(A) (emphasis added). That proper final judgment in an APA challenge is separate from considerations that might apply to preliminary injunctions, though Defendants' footnote tries to merge the two contexts. HHS Opp. at 45 n.12.[7] Ordinary vacatur is the correct final remedy here to set aside this improper rulemaking.

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[7] Defendants' footnote does not request remand without vacatur, much less try to establish the stringent predicates for that rare remedy. *See Wood v. Burwell*, 837 F.3d 969, 976 (9th Cir. 2016) ("remand without vacatur is a remedy used sparingly in this circuit").

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B. Trying to Limit a Remedy to Plaintiffs or to Salvage Bits Is Improper

HHS's suggestion, in passing, that vacatur of its rulemaking should "extend only to the Plaintiffs" has no basis in law. HHS Opp. at 45 n.12. Courts have repeatedly "foreclosed this audacious argument." *New York v. HHS*, 2019 WL 5781789 at *71. When an agency has violated the APA, the harm does not lie merely with the plaintiff; instead, the plaintiff has shown that "the agency has breached the plaintiff's (and the public's) entitlement to non-arbitrary decision making." *See Make the Rd. N.Y. v. McAleenan*, 405 F. Supp. 3d 1, 72 (D.D.C. 2019). "Consequently, to provide the relief that any APA plaintiff is entitled to receive for establishing that an agency's rule is procedurally invalid, the rule must be invalidated" for all. *Id.*

Similarly, Defendants argue that the Court should limit vacatur to "specific provisions of the Rule," despite the arbitrariness that infects HHS's entire undertaking here and without attempting to identify any isolated provisions that HHS contends could remain. HHS Opp. at 45 n.12. Plaintiffs show arbitrariness in this rulemaking as a whole. NFPRHA Mot. at 10-11, 68-72. Moreover, as in the refusal regulations case, the APA violations here are so "numerous, fundamental, and far-reaching" as to expose the lack of APA integrity in this "rulemaking venture itself." *New York v. HHS*, 2019 WL 5781789 at *69.

Any attempt to "leave standing isolated shards of the Rule that have not been found specifically infirm would ignore the big picture: that the rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors." *Id.* Such an endeavor would inevitably "undercut the whole

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structure of" this highly interconnected, multi-part Rule. *See Flores v. Barr*, 407 F. Supp. 3d 909, 931 (C.D. Cal. 2019) (refusing to require those governed by remnants to "to parse through pieces of regulations disembodied from their animating purpose"); *see also Humane Soc'y of United States v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017) (when there are "major shortcomings that go to the heart of the" agency's actions and those deficiencies played a "serious and pervading role… in the agency's decisionmaking," vacatur of the entire rule is appropriate).

C. The Court Has Already Rejected the Request to Stay Proceedings

HHS also tries to avoid vacatur of the Rule by again urging the Court to stay the district court proceedings while the Ninth Circuit considers preliminary injunction-related issues. HHS Opp. at 42-44. Defendants have made this request twice before, and each time the Court has determined that the district court litigation should continue to move forward. *See* ECF No. 86 (June 14, 2019, order denying motion to stay proceedings); ECF No. 124 (minutes of November 13, 2019, status conference that maintained summary judgment schedule and noted that the schedule was determined, *inter alia*, with an eye toward the Rule's March 4, 2020, implementation date for physical separation).

Denial of Defendants' renewed stay request is even more critical now, on the eve of the March 4, 2020, deadline. Were physical separation to take effect, its high costs and strong pressures to either exit the Title X network or unduly limit existing, effective health care practices would injure NFPRHA members across the country—along with other Title X grantees, subrecipients, their provider sites, and their patients. *See* NFPRHA Mot. at 36-50 (including citations to administrative

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record evidence on the harmful impact of physical separation).[8] A "stay is not a matter of right" and represents "an intrusion into the ordinary processes of administration and judicial review." *Sierra Club v. Trump*, 929 F.3d 670, 687 (9th Cir. 2019) (internal quotation omitted). The party requesting a stay bears the burden of convincing the court that circumstances demand it, which is a particularly high burden when, as here, the opposing party will be harmed. *See Lockyer v. Mirant Corp.*, 398 F.3d 1098, 1112 (9th Cir. 2005) (under such circumstances, the stay movant must show, among other things, its own "clear case of inequity or hardship") (citation omitted). But Defendants here do not offer *any* alleged harm to HHS from this Court proceeding in the ordinary course to resolve the cross-motions for summary judgment without delay. *See id.* ("being required to defend a suit" does not cause the necessary "clear case of inequity or hardship").

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[8] Defendants' description of the parallel California district court actions, HHS Opp. at 44, is now outdated; the plaintiffs there are also moving forward with a recently-ordered summary judgment briefing schedule to try to avoid the additional harms that March 4, 2020, will bring. *See Essential Access Health v. Azar*, No. 3:19-cv-1195, ECF No. 130 & 131 (January 15, 2020, scheduling order). The district court in Baltimore has also recently held a hearing on the motion for summary judgment against the Rule there, focusing on the Baltimore plaintiffs' arbitrary and capricious rulemaking claims. *See Mayor and City Council of Baltimore v. Azar*, No. 19-cv-1103 (D. Md.), ECF No. 91 (hearing held January 27, 2020).

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Importantly, a preliminary injunction appeal affects "'the rights of the parties only until the district court renders judgment on the merits of the case, at which time the losing party may again appeal.'" *Melendres v. Arpaio*, 695 F.3d 990, 1003 (9th Cir. 2012) (quoting *Sports Form, Inc. v. United Press Int'l, Inc.*, 686 F.2d 750, 753 (9th Cir. 1982)). This case is ready for final merits adjudication in this Court and there should be no delay in that occurring. While Defendants suggest that the Ninth Circuit might provide "guidance" by addressing the appeal now before it, HHS Opp. at 44, that appeal is by its very nature preliminary and cannot obviate the need for this Court to render a substantive, merits ruling. Indeed, the administrative record was produced after this Court granted the preliminary injunction and is not part of the pending preliminary injunction appeal. Thus, the Court will be evaluating whether HHS's rulemaking is properly grounded in the record facts and justified by reasoned explanation from those facts in the first instance. The Court needs no guidance from the Ninth Circuit to recognize—as Plaintiffs have thoroughly shown on these motions—that HHS repeatedly acted arbitrarily, without reasoned basis, and contrary to the record evidence in adopting the Rule. Accordingly, the Rule should promptly be vacated.

D. Defendants Have Offered No Basis to Stay Judgment for Plaintiffs

Finally, Defendants' suggestions for delay also include the bare request that if the Court grants summary judgment to Plaintiffs, it should "stay the effect of its order pending appeal to avoid the need for Defendants to consider seeking emergency appellate relief." HHS Opp. at 44. Defendants fail to explain any need for "emergency appellate relief." Vacating the Rule would simply reinstate the

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prior, long-standing Title X regulations under which HHS selected all current Title X grantees and those grantees agreed to operate. And, as discussed above, a stay is not a matter of right. Defendants bear the burden of showing that a stay pending appeal is justified, considering the parties' likelihood of success, the balance of equities, and the public interest. *Washington v. Trump*, 847 F.3d 1151, 1164 (9th Cir. 2017) (quoting *Nken v. Holder*, 556 U.S. 418, 433 (2009)). If this Court grants Plaintiffs summary judgment, however, it will have determined that *Plaintiffs* succeed on the merits and that HHS has violated its duties to the public in promulgating this Rule, harming Plaintiffs and others—not Defendants. Defendants' unsupported anticipatory request for a stay pending appeal should be denied.

CONCLUSION

For all the reasons set forth here and in Plaintiffs' initial motion papers, the Court should grant summary judgment to Plaintiffs, deny summary judgment to Defendants, and immediately vacate the Rule in its entirety.

DATED: February 3, 2020

By: /s/ John Midgley

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the court's CM/ECF system, which will serve a copy of this document upon all counsel of record.

Dated: February 3, 2020

/s/ Ruth E. Harlow
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